



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

SEP 30 1997

OFFICE OF WATER

Mr. Robert W. Hall Nevada Environmental Coalition P.O. Box 370956 Las Vegas, Nevada 89137

Dear Mr. Hall:

Thank you for your letters dated August 19, 1997, and September 5, 1997, to Administrator Carol M. Browner, of the Environmental Protection Agency (EPA) regarding ammonium perchlorate contamination of water supplies. The initial letter requests that EPA respond to 26 questions concerning the health effects associated with perchlorate contaminants found in Las Vegas drinking water sources, while the second letter reiterates seven key concerns. The responses to the first set of questions, which also responds to concerns posed in the second letter, are detailed in the enclosed document.

Ammonium perchlorate, a man-made inorganic salt used as a component of solid rocket fuel, was discovered in 22 drinking water supply systems throughout California. Additionally, 5 to 9 (ppb) perchlorate have been detected in the Colorado River, the drinking water supply to over 10 million people in California, Arizona and Nevada. The State of California and the Southern California Metropolitan Water District traced the source as far upstream as the outlet of Lake Mead. The major manufacturing facility for perchlorate, Kerr-McGee in the BMI industrial complex, located in Henderson, Nevada, is in an area draining into Lake Mead.

EPA has actively pursued a program of research and assessment to address this issue. The Nevada Division of Environmental Protection (NDEP) is the lead agency that is investigating the distribution of perchlorate in both surface and ground water. EPA and California are also investigating other sites outside of Nevada. Under the authority of the Nevada Water Pollution Control law and federally delegated Clean Water Act, NDEP will require all potential sources to define the extent to which surface and ground water have been impacted by perchlorate. In addition, to fill data gaps, a 90-day oral toxicity study of perchlorate drinking water exposure is currently being conducted by the Air Force and Aeroject Inc. Preliminary data from this study on perchlorate exposure to rats is expected in the last quarter of fiscal year 1998.

There are ongoing activities on perchlorate to fill data gaps which currently exist. The new information generated will provide us a better understanding of the potential effects of exposure to perchlorate in drinking water.

I hope I have adequately addressed your concerns about ammonium perchlorate contamination of water supplies. If you any questions, please contact me, or have your staff call Bill Diamond, Director of the Standards and Risk Management Division, at 202-260-7575, or Jeanette Wiltse, Director of Health and Ecological Criteria Division, at 202-260-5389.

Sincerely,

Robert Perciasepe
Assistant Administrator

Bob Persiases

Enclosure

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The following responses address questions and concerns on the health effects of perchlorate contaminants in drinking water, posed in both letters dated August 19, 1997 and September 5, 1997.

1. Does EPA have any scientific data other than data referenced herein that supports with credible science, a provisional RfD? If so, please provide the data. (Note: Where the word "scientific" is used herein, we mean to include immunotoxicology in the definition of that word.)

An RfD (reference dose) is an estimate of a daily exposure to the human population that is likely to be without appreciable risk of deleterious effects over a lifetime. The RfD is an estimate and may not be completely protective of every individual within a highly variable population, but neither are exposures above the RfD necessarily unsafe. Some individuals may have better adaptive or protective capacities than others and responses may vary with age and state-of health; thus, individuals respond differently to toxicants exposure. An RfD value is derived from a No-Observable-Adverse-Effect Level or Lowest-Observable-Adverse-Effect Level approach by accepted, current risk assessment practice used by EPA. You refer to a 1995 document entitled: Risk Assessment Issue Paper for: Derivation of Provisional Non-cancer and Cancer Toxicity Values for Potassium Perchlorate (CASRN 7778-74-7) written by the National Center for Environmental Assessment of the Office of Research and Development, EPA. Research reports pertinent to the derivation of the provisional noncancer and cancer toxicity values for perchlorate were identified from computer literature searches of the following databases: MEDLINE, TOXLINE, CANCERLIT, TSCATS, RTECS and HSDB covering the period 1965-1992. In addition, references cited in an ICF Technology, Inc. report entitled On the Toxicity of Perchlorates (undated) were retrieved and examined for the derivation of the provisional RfD for perchlorate. To EPA's knowledge, no newer data have been generated to date that would change the current provisional RfD.

2. Does EPA agree that the only ethical answer to the toxicity of perchlorate question is that there are not enough data to answer perchlorate toxicity questions with any answer other than we don't know?

The confidence in the data base for perchlorate is low to medium, as stated in the Risk Assessment Issue Paper for: Provisional Non-cancer and Cancer Toxicity Values for Potassium Perchlorate. The effect of chronic exposure to relatively high doses of perchlorates has been studied in humans with hyperthyroidism and animals, but data concerning long-term, low-exposure effects are limited, as are data regarding the possible effects of perchlorate on the hematological system. The data base also lacks developmental and 2-generation reproductive studies. An uncertainty factor of 1000 was proposed for the RfD derivation, which includes 10 for the use of a less than chronic study, 10 for the protection of sensitive individuals and 10 to account for data base deficiencies including limited data for subchronic and chronic administration of low doses

of perchlorate, the lack of developmental and 2-generation reproduction studies and limited hematological effects information.

These uncertainty factors are considered to be public health conservative and are in accord with standard EPA practice for data bases of this quality. The purpose of uncertainty factors is to provide some compensation for limitations in toxicological data. In effect, when important data are missing ("we don't know"), uncertainty factors are added to lower the RfD, providing additional public health protection.

3. Are there any circumstances in which EPA supports the delivery of ammonium perchlorate or rocket fuel oxidizer contaminated drinking water to consumers? If so, what are they?

The Agency is not a proponent of ammonium perchlorate contaminants in drinking water. Nevertheless, contamination of water sources from anthropogenic sources does exist. The provisional RfD for perchlorate was developed to support decisions to control this type of contamination.

4. Is EPA's water contaminant scientific research based upon the discipline of toxicology or immunotoxicology? Please explain your answer.

EPA's water contaminant scientific research is based upon the discipline of toxicology, which includes immunotoxicology.

5. Does EPA agree that with regard to press releases and public statements, the words "trace", "tiny", "small", or "one part per billion" is equal to one drop in a 55,000-gallon container, or similar words are scientifically misleading and not useful in bringing clarity to toxic chemical issues, particularly from the immunotoxicological point-of-view. Stating this another way, aren't such words more appropriate to a program of disinformation than to an EPA information release or statement?

Contaminants found in water are commonly found in very small amounts. Concentrations of these contaminants are expressed in parts-per-million, parts-per-billion, or parts-per-trillion. These expressions of concentration are not absolute amounts, but an indication of how much a contaminant is found in drinking water. One part-per-billion means that for every billion parts of a solution or mixture, there is 1 part of the substance being measured. Other equivalents of parts-per-billion include: 1 microgram in a kilogram and 1 drop in a 10,000-gallon tank. Again, the unit of parts-per-billion is to provide clarity and information about the relative contribution of the subject contaminant in the drinking water source, in comparison to other contaminants that may or may not be present.

6. Does EPA agree that finding a provisional RfD for perchlorate was a scientific and ethical error?

The provisional RfD for perchlorate was derived according to approved and recognized methodological standards, based on sound scientific data available at that time. The human and animal data reviewed in the RfD document demonstrate that perchlorate can inhibit the production of iodide containing thyroid hormones by competitively inhibiting iodide accumulation in the thyroid. The short-term consequence of this action is a response by the pituitary gland to produce thyroid stimulating hormone (TSH), which in turn stimulates diffuse cell division and growth of the thyroid gland. With long-term thyroid stimulation, diffuse thyroid hyperplasia may progress to nodular proliferation of follicular cells and eventually to neoplasia. Based on this information, the RfD was derived with the No-Observable-Adverse-Effect Level (NOAEL) from a study performed by Stanbury and Wyngaarden (1952) of 0.14 mg/kg/day.

7. Does EPA intend to take regulatory action to stop California from using the 18 ppb provisional RfD?

No. Based on current information, the concentration of 18 ppb (0.018 mg/L) of perchlorate in drinking water is adequately protective of public health. EPA's concentration range of perchlorate (4 ppb to 18 ppb in drinking water) is based on EPA's 1995 revised oral RfD values of 1E-4 to 5E-4 mg/kg/day applied to an adult (70 kg who ingests 2 L of water/day; 5E-4 x 70 kg/2L = 17.5E-3 mg/L).

8. Are contaminants such as ammonium perchlorate lawful at any level in potable water pursuant to current EPA regulations or statutes? If so, please identify these statutes or regulations.

To date, there are no national primary drinking water regulations for perchlorate. There are such regulations for other contaminants pursuant to the Safe Drinking Water Act. These drinking water regulations can be found in the Code of Federal Regulations, Title 40, Part 141.

9. Is EPA aware of the study conducted in Nevada between 1970 and 1974 that found perchlorate in shallow ground water layers in the industrial area near Henderson, Nevada? If so, what did EPA do about that finding from that point to this date?

Nevada officials have recently informed the Agency that water was sampled from the vicinity of the waste ponds in an industrial area of Henderson, Nevada sometime between 1970 and 1974. We understand that these samples were analyzed for ammonium, not for perchlorate, and that the results were in the range of 100-150 ppm of ammonium. It is not known if the source of this ammonium is dissolved ammonium perchlorate. EPA does not have the original data that forms the basis of this information.

10. Does EPA agree that the current situation requires immediate and decisive cleanup action?

EPA has publicly emphasized that the primary objective in dealing with the perchlorate contamination of Lake Mead and the Colorado River is to stop the source, clean it up and prevent it from being a problem in the future. The parties responsible for the release of perchlorate will be held financially liable for the cleanup costs. Preliminary investigations into contamination in the groundwater have started, and are being overseen by the Nevada Division of Environmental Protection with EPA assistance. A more formal series of work plans for a thorough investigation and action plan will be developed using the preliminary information.

11. Does EPA agree that perchlorate plants should not be located anywhere they can theoretically contaminate a potable water supply?

Decisions concerning the location of industrial facilities are the responsibility of state and local land use regulating agencies. EPA plays a role, along with state and local agencies, in the regulation of transport, storage and disposal of hazardous materials, and in protecting the air, water and land resources from improper discharges resulting from operation of these facilities.

12. Does EPA agree that breathing water vapor in a shower containing perchlorate theoretically may be more dangerous than drinking the same water as a result of the more immediate access to the blood stream through the lungs?

Perchlorate is a dissolved, and dissociated anion and is not a volatile compound, but a number of water contaminants that are volatile could diffuse from water into the air where they may be inhaled. The net effect of volatilization upon total exposure to volatile contaminants in water is not easy to determine. Although several approaches can be found in the literature, including various models that have been used by EPA, the Agency currently does not have a proposed methodology for explicitly incorporating inhalation from volatilization exposure from household water uses in the derivation of health-based criteria. The Agency is currently exploring the effect of volatilization upon exposure to drinking water contaminants.

13. Does EPA have any scientific or other information to indicate the type of municipal and home water cleansing units that may be effective against perchlorate?

The Agency does not have information on the effectiveness of home water treatment units in removing perchlorate. EPA does not directly regulate the manufacture, distribution, or use of home water treatment units, nor does the Agency test or evaluate them.

14. Is EPA aware that the poor and many so-called middle-income families in Nevada probably do not have access to reverse osmosis water decontamination units? What does EPA recommend with regard to the fact that public buildings including schools and hospitals, commercial businesses including restaurants, and government building do not have reverse osmosis units for their drinking water? Are those who drink from R/O units taking less risk than those who must drink from the facilities listed above?

Most Americans receive their drinking water from public water systems. Provided these systems are in compliance with Federal and State standards, EPA believes that home treatment for health protection is rarely necessary.

15. There is evidence that perchlorate may have contaminated Las Vegas drinking water since World War II. Does EPA intend to investigate the failure of municipal officials and agencies to regularly test for perchlorate since the contamination information was either known to them, or should have been known to them?

Perchlorate has not been identified as a chemical specifically regulated by Federal statutes. EPA's focus is to address the current threats to public health and the environment, prevent future releases and hold the responsible parties liable for the cleanup costs. Currently, there are no existing Federal regulations that require testing of water for perchlorate.

16. What role has EPA had in detecting perchlorate in Las Vegas water since EPA's inception? Please provide us with copies of all EPA data that supports your answer to that question.

The drinking water program recently became aware of perchlorate contamination as an issue based on the findings from the California Department of Health Services which are posted on their website, "http://www.dhs.cahwnet.gov/prevsrv/ddwem/index.html". The EPA has no other responsive data.

17. What is EPA's position on one State using another State's provisional RfD in a situation such as the current perchlorate situation?

RfD's are based on toxicological data that are not different from State-to-State and are, therefore, appropriate for general consideration. Risk management decisions may vary from State-to-State according to the authorities and decision-making discretion of State officials.

18. Will EPA become financially and legally involved in a Las Vegas clean-up of perchlorate?

EPA is actively engaged in providing technical expertise and regulatory oversight in the cleanup of the perchlorate contamination in Henderson, Nevada. EPA is also coordinating efforts to extend our knowledge of the toxicology, treatment capabilities and analytical methodology for perchlorate.

19. What are the synergistic effects of perchlorate with other toxic chemicals known to be in the Colorado River and Lake Mead? Tests are showing high levels of Radon in Las Vegas potable water. What is EPA's position on the issue of Radon in combination with perchlorate?

There are no published, peer-reviewed data on potential synergistic effects of perchlorate with other toxic chemicals known to be in the Colorado River and Lake Mead. Literature searches, performed to date, have not identified information about this topic.

20. On what credible scientific basis have assurances been given to the parents of children and pregnant women regarding perchlorate?

As was stated in response #2, the data base for perchlorate lacks developmental and 2-generation reproductive studies. This is why an uncertainty factor of 1000 was proposed for the RfD derivation, which includes an uncertainty factor of 10 for the use of a less than chronic study, 10 for the protection of sensitive individuals (e.g., children, people on low iodine diets, or deficient in iodine uptake and people who have hypothyroidism) and 10 to account for data base deficiencies including limited data for subchronic and chronic administration of low doses of perchlorate, the lack of developmental and 2-generation reproduction studies and limited hematological system.

21. Does EPA intend to take action against the person or persons who are responsible for perchlorate being in the Colorado River and Lake Mead?

EPA would certainly be concerned and take appropriate action consistent with our legal authority to address any pollutant that poses a risk to public health and the environment. As we learn more about the source of perchlorate and its mode of transmission to the environment, EPA can use available regulatory and enforcement tools to take appropriate action. EPA or an approved state environmental agency, for example, could use Clean Water Act authorities to regulate or take enforcement action against point sources of pollutants found in United States waters.

22. What testing frequency does the EPA consider adequate for perchlorate under the circumstances related herein?

See response for question #15.

23. What wells should be closed in the Las Vegas Valley as a result of perchlorate?

As no Federal regulations are in effect for the contaminant, decisions as to appropriate action are in the domain of State and local authorities.

24. Does EPA, or does EPA know of any other federal agency that is in a position to brief the medical community in Las Vegas with regard to health issues in relation to perchlorate?

EPA's role is to address and control the sources of contamination, to oversee the toxicological investigations, and to assist with the development of treatment technologies. EPA has begun coordination with other States in Region 9 and nationwide to alert drinking water regulators to the threat of perchlorate.

25. Does EPA have or does EPA intend to set up a registry to report those suspected to have health effects from perchlorate? If not, why not?

EPA does not maintain such registries for environmental contaminants. Currently, the California Department of Health Services requires drinking water utilities to provide written notification to public users when the 18 ppb upper action level has been exceeded. Accompanying this notice is information about perchlorate and possible health effects to sensitive populations, such as children, pregnant women and people with hypothyroidism.